

This page Is Inserted by IFW Operations
And is not part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of
The original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
Please do not report the images to the
Image Problem Mailbox.**

THIS PAGE BLANK (USPTO)

EUROPEAN PATENT OFFICE

No. Of Publication: 0162005
A1

EUROPEAN PATENT APPLICATION

APPLICATION No. 85730058.4 Int. Cl. A 61 F 2/34, A 61 N 1/32

Date of application: 04/13/85

Priority: 04/13/84 DE 3414514

Applicant: **BIOTRONIK Meß- und Therapiegeräte GmbH
& Co Ingenieurbüro Berlin, Slevversufer 8,
D-1000 Berlin 47 Germany**

Date of announcement of the application 11/21/85
Patent page 85/47

Inventor: **Prof. Dr. Welgert, Manfred, MD
Cimbernstrasse 22, D-1000 Berlin 38 Germany**

Inventor: **Dr. Werhahn, C., MD
Bayernallee 43, D-1000 Berlin 19 Germany**

Named agreement states: **Austria, Switzerland, Germany, France, Lithuania**

Representative: **Christiansen, Henning, Engineer
Unter den Eichen 108a, D-1000 Berlin 45 Germany**

EP 0 162 005 A1

Screw Pan for an Artificial Hip Joint

Screw pan (1) for an artificial hip joint, in which at least in the thread base (2) a conducting area (13) is provided, which is in conducting contact with a tension source (30) for bone stimulation.

[outline]

0162005

BIOTRONIK Meß- und Therapiegeräte
GmbH & Co Ingenieurbüro Berlin
D-1000 Berlin

B84.1-EU

April 12, 1985

Screw Pan for an Artificial Hip Joint

Description

The invention refers to a screw pan of the type described in the wider elaboration of claim 1.

From DE-PS 23 15 517 a hip joint prosthesis is known, which utilizes electric electrodes isolated from each other in the shank area, which in case of a loosening of the prosthesis allow, by means of low frequency alternating currents, to stimulate the formation of the bone tissue anew, in order to thus restore a satisfactory connection with the bone.

The disadvantage in the known prosthesis and similar devices for bone stimulation by means of current application through electrodes, is that an application for the hip pan is impossible, and that moreover, through the arrangement of the various electrodes in the shank area, only an accidental, local, very variable current distribution is achievable, so that a stimulation of bone growth is not achievable for a larger area. Moreover, the application of a stimulation current with changing polarity is not suitable.

The invention described in claim 1 has the task of providing a pan of the indicated kind, which by means of stimulation of bone growth supports the affixing of a pan in such a manner, that a firm fit is ensured after a relatively short time.

The invention is based on the realization, that by means of direct current stimulation, in which the implanted electrodes form the cathode and the skin surface the anode, over virtually the entire external bearing surface of the implant a bone growth is to be achieved, which would allow a secure growth already in the directly on the implant following phase, in which the stimulation of the bone favors tissue growth – over the total surface equally distributed – limited to smaller zones or areas, in which the formation of bone tissue has a maximal effect on the stabilization of the implant.

By means of a hip pan that can be screwed on it was hitherto impossible, to form individual areas of the surface as electrodes, because the entire outer surface, in conducting connection with the bone, is shaped as screw thread and can thus hardly allow the carrier flanks to tack on electrode surfaces or to affix them in any manner.

It was nevertheless found, that a stable seat of a screw pan can be achieved even when, the base of the coil is filled with new bone tissue. In order to facilitate an easy winding and a suitable screw thread, the spiral-shaped groove is cut deeper than it is to be filled by the screw thread, especially as the point area of the screw thread flank, due to the small carrying cross section, contributes only slightly to the power transmission in a screwed on screw thread. By means of the fact that this screw-facilitating free area – in a preferred improvement of the invention – is provided with a circular wire, it is possible to obtain, that the point area of the screw thread not filled out by material, can be filled with bone tissue, thus “jamming” the screw thread, so that an unwinding, or undesired turn on a small angle is securely prevented. This mechanism is also effective when the pan – in conic formation of the screw thread – is not fully screwed on, as in this case, by means of the stimulated bone growth, a fastening of the loose seat is achieved.

In other preferred developments of the invention, an effective electrode surface is provided also in vertically running grooves - threading the screw thread crosswise - which can, if necessary, occur by means of a corresponding shift of the wire forming the electrodes inside the grooves. Whereas the base of the screw thread of the screw part is wedge-shaped sharp, the outward facing part of the profile is preferentially blunted or rounded in trapezoidal shape. If an especially tight fit of the prosthesis seat is desired in a particularly short period, by means of callus formation, additional contributory electrode wires can be fitted in a groove of the side edge of the surface of the outer cone of the trapezoid cross section.

Thus the increased stability of the seat by means of "jamming" of the screw thread is also insured. As the bone growth stimulation here represented, increased within a screw thread the screw thread friction, thus ensuring a winding security, the attainable tightness is greater than in the case of stimulation of bone growth areas, which are subject to loading through shear force or traction. By means of the jamming aimed at by the invention, the available bone surface is maximally strengthened with a minimal volume of additional amount of bone tissue increased through stimulated growth.

In accordance with other advantageous developments of the invention, the contact elements for the power supply in different places independent of the position reached though the screwing of the pan attained position, are always accessible through the access side in the operation. Thus it is particularly advantageous, that the wire forming the electrodes can be stretched without problems through the cylinder-shaped formation of a reception fitting shape of the connection terminal over a rotation motion. The end of the cylindrical pivot is thus preferentially to be provided with a slot or a corresponding fitting shape, which allows for a turning moment transfer by means of a tool.

Further advantageous developments of the invention are indicated in the sub-claims. They are further described in the following representation together with a preferred version. Figure 1 illustrates a version of the invented pan in a view from below. Figure 2 illustrates the entire pan in a cross section with a detail represented in Figure 2a, in which the section surface of Figure 2 is observable from Figure 1. Figure 3 illustrates the sample of the pan of the said invention according to Figure 1 in a side view, where the area of a connection terminal for the electrode attachment is represented in cross section.

The invention is from now on to be explained in simultaneous reference to the various figures, where as required, the figure is indicated which illustrates the referred element most clearly.

The body 1 of the pan consists of a body-tolerant plastic, which has the necessary strength for the indicated purpose. It is shaped in a cone-blunt form in which the leading front surface in the screwing process has a smaller diameter. The provision of a screw thread 2 is fundamentally known as is the inner calotte-shaped part 3 for a joint ball. Additionally designed are tool grooves 4, 5 and 6, which are moved by a 120 degree shift on the perimeter, and which serve for the turning moment transfer during an introduction of a screw tool.

Grooves 7 to 12, which turn crosswise to the screw thread, help protect the pan from unwanted rotation in the first phase after the operation, where the grooves in a possible self-cutting version help with the intake of bone shavings created during the screwing action. The version illustrated here is however introduced in a precut screw thread, which corresponds to the shape thereof on the outer surface of the pan. The screw thread is thus precut, so that the shapes generated in the bone are formed with pointed angles wedge-shaped, whereby in the cut grooves there is still material remaining. The section 14 to be cut into the bone is represented in Figure 2 for the left screw thread area in the illustration as partial cross-section.

At the base of the screw thread runs a wire spiral 13 as electrode, which forms the stimulation electrode. This spiral connects three connection terminals, designated with numbers 15, 16 and 17. All terminals 15 to 17 are electrically on the same potential and can be selectively joined with a connection – depending on the position of the pan in the screwed in position, as illustrated in figure 2a in enlarged form. Whereas connection terminals 15 and 16 only touch the wire, which is led through a hole at the terminal designed for this purpose, to the corresponding cylindrical part, which is located in a corresponding shape of the body of the pan, terminal 17 also connects to the upper part of the electrode wire 13, so that with the rotation of the corresponding cylindrical element 18, by means of intervention in a slit-shaped fitting, the wire can be stretched from above, whereas it was placed only loosely during the assembly.

The fitting, into which element 18 was introduced, is so proportioned, that in the various positions which can be reached in the stretching, a wedge fit results. Contact elements 19, 20 and 21 can be introduced from below into the cylindrical contact elements and are secured in it through flexible contact grinder 22 and 23 (Figures 2, 3) and through leading pieces 24. Elastic plugs (one plug 25 in figure 2 is an example) close the fittings inside the pan after the introduction of the terminal connections.

The diameter of the wire forming the electrodes is so measured, that under the consideration of the electrolytes formed by the body fluid in the body in the corresponding set tension a current density of approximately 4 mA/cm^2 results – applied to the bone surface.

The enlarged end of the connection pivot 19 illustrated in figure 2a indicates, that it is shaped like a cone and pointed, and in the area of the full diameter presents a surrounding wire 27, in which the inlet spirals of the electrode connection is pulled inwardly through the tensile stress of the tube 29 surrounding the spiral 28. In this manner a connection system is obtained, which by simple means functions securely and reliably and also provides a sealing of the body fluid. The electrode connection can be obtained within the operation phase without particular effort and if necessary, modified.

A direct current source 30 is connected with a connection terminal of the pan 1, whose electrode surfaces form the cathode, whereas the counter-pole is formed by means of a skin anode.

Figure 2 illustrates, that the electrode wire lies in a cavity, where it remains during the gearing of the conic screw thread of the pan in the tissues cut into the bones. Precisely the bone growth stimulated in this cavity ensures – as initially illustrated – an optimal tightening of the pan seal, as bone growth is stimulated here in one area, which on the one hand secures the ease of the screw thread during screwing, and on the other, after it is filled with bone tissue, ensures that the screw thread cannot be further rotated.

In other versions – not illustrated in the drawing – the wire can also be led through vertical grooves 7 to 12, so that through the bone tissue formed here, an additional lock against excess rotation is created.

A bone tissue stimulation in this area is generally unnecessary, as the growth, due to the larger cavity to be filled, would also require additional time. Furthermore there is the possibility to provide more grooves in the elevated parts of the screw thread of the pan, in which wires can be introduced, so that the corresponding area, on the side of the bone tissue at the point of the screw thread to be cut there, can also be filled with bone mass generated through stimulated growth.

The invention is not limited in its version to the above example. Rather, a multitude of variants are possible, which make use from the illustrated solution, also in fundamentally differently designed versions.

Claims

1. Screw pan for an artificial hip joint, characterized by the fact that in deeper parts of the screw thread (14) leading areas (13) are provided, which by means of a direct current source (30) is in leading connection for the purpose of bone stimulation;
2. Screw pan according to claim 1, characterized by the fact that the leading areas are formed by a wire (13), which runs along the screw thread ground under initial tension.
3. Screw pan according to claim 2, characterized by the fact that at least one cylindrical pivot (15 to 17) is provided, which is introduced in the pan (1) with clamp fit, and for the spanning of the wire of one of its ends respectively a middle section holding it through multiple winding on its outer surface.
4. Screw pan according to one of the preceding claims, characterized by the fact that the cylindrical pivot (15 to 17) is fitted into an area of the pan (1) and presents at one of its ends an area reachable through an opening in the body of the pan for a turning moment connection.
5. Screw pan according to one of the preceding claims, characterized by the fact that the pan is endowed with vertically running grooves (7 to 12) in the screw thread area (13).

6. Screw pan according to claim 5, characterized by the fact that at least in the area of the groove ground, leading areas are also provided.
7. Screw pan according to one of the preceding claims, characterized by the fact that a vertically running wire is provided.
8. Screw pan according to one of the preceding claims, characterized by the fact that with the cylindrical pivot a contact element (19) is connected as connection for an inlet.
9. Screw pan according to one of the preceding claims, characterized by the fact that several cylindrical pivots (15 to 17) which are in contact with the surrounding wire (13) are distributed on the perimeter of the pan, which provide a connection (19 to 21) for the inlet.
10. Screw pan according to one of the preceding claims, characterized by the fact that the connections (19 to 21) with a 120 degree shift are arranged on the outer perimeter of the pan (1) in the back area, – seen in the winding direction.

11. Screw pan according to one of the preceding claims, characterized by the fact that the connections (19 to 21) are pointed at their ends and present a surrounding groove (27), in which the elastic spirals (28) of the inlet provided with an insulating material (29) are embedded thus providing a protection against unwanted loosening.

12. Stimulation device for a screw pan according to one of the preceding claims, characterized by the fact that the screw pan forms the cathode, while the anode is provided on the skin surface.

EUROPEAN PATENT OFFICE

No. Of Application: 0 162 005

EUROPEAN SEARCH REPORT

EP 85730059.4

Relevant documents

Category – Document Identification by means of provision of, as needed, the appropriate parts

Claim Classification of Application

D, A DE – C2 – 2 315 517 (KRAUS) 1,2 A 61 F 2/34

* claims 1, 2 *

P, A DE – A1 – 3 240 592 (KRAUS) 1 A 61 N 1/32

* claim 1 *

Searched areas (Int. Cl. 4)

A 61 F

A 61 N

The above search report was made for all patent claims.

Search area

Date of conclusion of search

Examiner

VIENNA

07/26/1985

MIHATSEK

CATEGORY OF THE LISTED DOCUMENTS

X: Of special importance in themselves

Y: Of special importance in relation to another publication in the same category

A: Technological background

O: Other than written publication

P: Intermediate literature

T: Theories or Principles on which the invention is based

E: Older patent document which was nevertheless made public on or after the date of application.

D: Document quoted in the application

L: Document quoted for other reasons

&: Member of the same patent type, concurring document.

[outlines: Fig. 1, Fig. 2, Fig. 2a, Fig. 3]

1. [Illegible text]

2. [Illegible text]

3. [Illegible text]

4. [Illegible text]

5. [Illegible text]

6. [Illegible text]

7. [Illegible text]

8. [Illegible text]

9. [Illegible text]

10. [Illegible text]

11. [Illegible text]

12. [Illegible text]

13. [Illegible text]

14. [Illegible text]

15. [Illegible text]

16. [Illegible text]

17. [Illegible text]

18. [Illegible text]

19. [Illegible text]

THIS PAGE BLANK (USPTO)